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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,488	11/13/2006	Shigehisa Wada	0599-0213PUS1	7587
2292 7590 08/17/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER HURST, JONATHAN M				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/570,488

Applicant(s)

WADA ET AL.

Examiner

JONATHAN M. HURST

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 22-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (US 7,441,666).

Regarding claims 22-26, and 28 Kim et al. discloses a method of preparing a solution by removing of biological components from a human derived biological components-containing solution which comprises subjecting the biological components-containing solution to at least two treatment steps; wherein the two treatment steps are (2) a step of removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve; and (3) a step of concentrating proteins by passing a portion of the solution through a porous separation membrane and retaining the portion of the solution that does not pass through the porous membrane. See Abstract and Col. 23 Lines 23-55 where a solution containing proteins is passed through a membrane module and during which at least a portion of proteins having a molecular weight greater than or equal to albumin are removed from the solution and also during separation at least some forms or weights of proteins are concentrated and retained by the membrane while other proteins which pass through the membrane are also concentrated and retained in some form. The treatment step (2)

and (3) is conducted using a porous separation membrane containing one or more substances selected from cellulose, cellulose a polyamide. (See Col. 6 Lines 55-65 and Col. 23 Lines 25-55 where a membrane comprising polyamide is used to perform steps 2), and (3)). The method further comprises a step wherein one or more substances selected from a group consisting of a polyethylene imine, an aminomethylpyridine, a polyphenol, a blue dye, a divalent metal ion, and an alkyl group-containing compound is fixed to the surface of the molecular sieve used in step (2). (See Col. 10 Lines 48-50 where a membrane to be used comprises a polymer and Col. 13 Lines 30-45 where polymer contains polyethylene imine and as such some will be fixed to the surface)

3. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Demmer et al. (US 6,001,974)

Regarding claim 29 Demmer et al. discloses an apparatus for preparing a solution by removing biological components having from a biological components-containing solution, wherein the apparatus comprises at least two modules joined by a flow path and selected from the following modules (2) a module for removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve; and (3) a module for concentrating proteins by passing a portion of the solution through a porous separation membrane and retaining the portion of the solution that does not pass through the porous membrane. (See Abstract, Fig. 1 and Col. 2 Line 37- Col. 3 Line 35 where a module 1 contains membranes which remove at least a portion of protein of larger molecular weight than

albumin and a second membrane module where some forms of protein are concentrated and retained).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 7,441,666).as applied to claims 22-26 and 28 above, and further in view of Comper (US 2002/0022236).

Regarding claim 27 Kim et al discloses all the claim limitations as set forth above as well as the method of preparing a solution according to the claim 22, wherein a dye is added to an aqueous solution in the step (2) in order to dye albumin (See Col. 23 Lines 25-55 where albumin coloring agent is used). Kim does not specifically disclose the use of a blue dye.

Comper discloses the use of a blue dye in order to detect albumin in a solution during a filtration process. (See [0085])

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a blue dye as described by Comper to the solution of Kim because the dye of Comper because the blue dye is able bind to albumin selectively over other unwanted compounds during detection (See Comper [0085]) and it fulfills the need for a

selective albumin coloring agent allowing for the detection of albumin in the solution as required by Kim. (See Col. 23 Lines 25-55).

While the reference does not explicitly disclose adding the blue dye before step (2) it is noted that selection of any order of performing disclosed process steps is prima facie obvious in the absence of new or unexpected results. See *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to dye the albumin containing solution before step (2), as it amounts merely to change of the order of performing disclosed process steps in the absence of new or unexpected results.

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Demmer et al. (US 6,001,974) in view of Kim et al. (US 7,441,666).

7. Regarding claim 30 Demmer et al. discloses all the claim limitations as set forth above as well as the apparatus for preparing a solution further comprising a liquid flow-

out path to-be for transporting the prepared solution (See Fig. 1 where pure albumin C' flows out from module 3 and is characterized). Demmer further discloses characterizing the protein solution which comes out of a flow-out-path of the apparatus using a number of techniques (See Col. 3 Lines 21-35) but Demmer does not specifically disclose the liquid flow-out path joined to a liquid chromatograph, an electrophoretic apparatus, or a mass spectrometer.

Kim discloses in column 21, lines 25-50 that one way to characterizing proteins is by passing through a chromatograph.

It is noted that it is very well known in the art, as shown by Kim, to analyze and characterize protein containing solutions using liquid chromatographs, electrophoretic apparatuses, or a mass spectrometers in order to understand the constituents and or determine purity of a said solution as described by Demmer and connecting the output of one device to the input of another device when a product is meant to be conveyed from said one to another is very well known in the art. Therefor it would have been obvious to one of ordinary skill in the art at the time of invention to connect the liquid flow-out path of Demmer to a liquid chromatograph, an electrophoretic apparatus, or a mass spectrometer in order to quickly and efficiently convey the product for analysis as is well known in the art and required by Demmer. In addition, the substitution of one known technique for another is clearly within the scope of the skilled artisan.

Response to Arguments

8. Applicant's arguments with respect to claims 22-30 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that "Kim '666 fails to disclose or suggest either treatment step (1) or treatment step (3) of the method of the present invention. Treatment step (1) requires that proteins be adsorbed on to a selectively hydrophobic substrate. Treatment (3) requires that a sample solution be passed through a porous separation membrane, and that the portion of the solution that does not pass through be retained. Thus, significant patentable distinctions exist between the present invention and Kim '666, such that above-noted rejections based on this reference should be withdrawn." It is the examiner's position that Kim teaches treatment step (3) because as a sample solution is passed through a porous membrane as described by Kim (See Kim Col. 23 Lines 25-55) the membrane blocks certain types of proteins from passing through and thus retains said certain types of proteins concentrating them on one side of the membrane. Since the amended claims only require 2 of the three steps to be performed and Kim teaches treatment step (2) by applicant's own admission (See Arguments and remarks PG. 13 para. 5) and step (3) as described above, the claims stand rejected over Kim.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 1797

/Michael A Marcheschi/

Supervisory Patent Examiner, Art Unit 1797